



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Jeffrey L. Browning, *et al.*

Serial No.: 10/040,281

Filed: November 7, 2001

For: *LYMPHOTOXIN-BETA, LYMPHOTOXIN-BETA
COMPLEXES, PHARMACEUTICAL
PREPARATIONS AND THERAPEUTIC USES
THEREOF*

Attorney Docket No.: BGN-B129CP2D2CN RCE

Group Art Unit: 1635

Examiner: Sean McGarry

MS RCE
Commissioner for Patents
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Alexandria, Virginia 22313-1450

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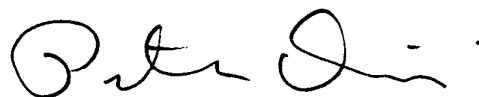
For the Examiner's convenience in reviewing this continuation application, Applicants submit a consolidated PTO Form SB/08, listing all references cited during the prosecution of the parent application. The present application is a Continuation of U.S. Serial No. 08/466,254, filed June 6, 1995, which is a Divisional of U.S. Serial No. 08/222,614, filed April 1, 1994, which is a Continuation of U.S. Serial No. 07/990,304, filed December 4, 1992 (Atty. Docket No. BGN-B129CP2D2CN). All references listed on the enclosed PTO Form SB/08 have been previously cited by or submitted to the Office in the prior application, and, in

accordance with 37 CFR §1.98(d), copies of the references are not enclosed but will be provided upon request.

This statement is not to be interpreted as a representation that the cited publications are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any publication herein be construed *per se* as a representation that such publication is prior art. Moreover, Applicants understand that the Examiner will make an independent evaluation of the cited publications.

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Respectfully submitted,
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Sheet	1	of	5	Attorney Docket Number	BGN-B129CP2D2CN RCE

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	A1	4,338,397	07-06-1982	Gilbert, <i>et al.</i>	
	A2	4,758,549	07-19-1988	Mitsubishi, <i>et al.</i>	
	A3	4,822,605	04-18-1989	Powell	
	A4	4,849,509	07-18-1989	Thurin, <i>et al.</i>	

FOREIGN PATENT DOCUMENTS						
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		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
	B1	EP 0367575	05-09-1990	Sankyo Company		

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	C1	Abe, Y., <i>et al.</i> "Expression of membrane-associated lymphotoxin/tumor necrosis factor-beta on human lymphokine-activated killer cells." <i>Jpn J Cancer Res.</i> 1991 Jan; 82(1):23-6.		
	C2	Abe, Y., <i>et al.</i> "Studies of membrane-associated and soluble (secreted) lymphotoxin in human lymphokine-activated T-killer cells in vitro." <i>Lymphokine Cytokine Res.</i> 1992 Apr; 11(2):115-21.		
	C3	Abersold, <i>et al.</i> "Internal amino acid sequence analysis of proteins separated by one- or two-dimensional gel electrophoresis after in situ protease digestion on nitrocellulose." <i>PNAS.</i> 1987; 84:6970-4.		
	C4	Aggarwal, B.B., <i>et al.</i> "Primary structure of human lymphotoxin derived from 1788 lymphoblastoid cell line." <i>J Biol Chem.</i> 1985 Feb 25; 260(4):2334-44.		
	C5	Akashi, M., <i>et al.</i> "Lymphotoxin: stimulation and regulation of colony-stimulating factors in fibroblasts." <i>Blood.</i> 1989 Nov 15; 74(7):2383-90.		
	C6	Anderson, W.F. "Human gene therapy." <i>Science.</i> 1992 May 8; 256(5058):808-13.		
	C7	Anderson, U., <i>et al.</i> "Characterization of individual tumor necrosis factor alpha- and beta-producing cells after polyclonal T cell activation." <i>J. of Immun. Meth.</i> 1989; 123:233-40.		
	C8	Andrews, J.S., <i>et al.</i> "Characterization of the receptor for tumor necrosis factor (TNF) and lymphotoxin (LT) on human T lymphocytes." <i>J Immunol.</i> 1990 Apr 1; 144(7):2582-91.		
	C9	Androlewicz, M.J., <i>et al.</i> "Lymphotoxin is expressed as a heteromeric complex with a distinct 33-kDa glycoprotein on the surface of an activated human T cell hybridoma." <i>J Biol Chem.</i> 1992 Feb 5; 267(4):2542-7.		

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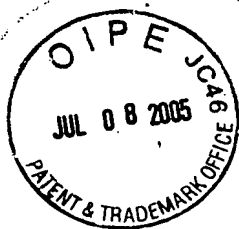
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	C10	Armitage, R.J., <i>et al.</i> "Molecular and biological characterization of a murine ligand for CD40." <i>Nature</i> . 1992 May 7; 357(6373):80-2.		
	C11	Badenhoop, K., <i>et al.</i> "TNF-alpha gene polymorphisms in type 1 (insulin-dependent) diabetes mellitus." <i>Diabetologia</i> . 1989 Jul; 32(7):445-8.		
	C12	Beutler, B., <i>et al.</i> "The history, properties, and biological effects of cachectin." <i>Biochemistry</i> . 1988 Oct 4; 27(20):7575-82.		
	C13	Bringman, T.S., <i>et al.</i> "Monoclonal antibodies to human tumor necrosis factors alpha and beta: application for affinity purification, immunoassays, and as structural probes." <i>Hybridoma</i> . 1987 Oct; 6(5):489-507.		
	C14	Browning, J.L., <i>et al.</i> "Studies on the differing effects of tumor necrosis factor and lymphotoxin on the growth of several human tumor lines." <i>J Immunol</i> . 1989 Sep 15; 143(6):1859-67.		
	C15	Browning, J.L., <i>et al.</i> "Lymphotoxin and an associated 33-kDa glycoprotein are expressed on the surface of an activated human T cell hybridoma." <i>J Immunol</i> . 1991 Aug 15; 147(4):1230-7.		
	C16	Cavender, D.E., <i>et al.</i> "Endothelial cell activation induced by tumor necrosis factor and lymphotoxin." <i>Am J Pathol</i> . 1989 Mar; 134(3):551-60.		
	C17	Cotran, R.S., <i>et al.</i> "Endothelial activation, its role in inflammatory and immune reactions." <i>Endothelial Cell Biology</i> . 1988; 335-47.		
	C18	Damle, N.K., <i>et al.</i> "Distinct regulatory effects of IL-4 and TNF-alpha during CD3-dependent and CD3-independent initiation of human T-cell activation." <i>Lymphokine Res</i> . 1989; 8(2):85-97.		
	C19	Eck, M.J., <i>et al.</i> "The structure of tumor necrosis factor-alpha at 2.6 A resolution. Implications for receptor binding." <i>J Biol Chem</i> . 1989 Oct 15; 264(29):17595-605.		
	C20	Eck, M.J., <i>et al.</i> "The structure of human lymphotoxin (tumor necrosis factor-beta) at 1.9-A resolution." <i>J Biol Chem</i> . 1992 Feb 5; 267(4):2119-22.		
	C21	Farrah, T., <i>et al.</i> "Emerging cytokine family." <i>Nature</i> . 1992 Jul 2; 358(6381):26.		
	C22	Fuh, G., <i>et al.</i> "Rational design of potent antagonists to the human growth hormone receptor." <i>Science</i> . 1992 Jun 19; 256(5064):1677-80.		
	C23	Goeddel, D.V., <i>et al.</i> "Tumor necrosis factors: gene structure and biological activities." <i>Cold Spring Harb Symp Quant Biol</i> . 1986; 51:597-609.		
	C24	Granger, G.A., <i>et al.</i> "Lymphocyte in vitro cytotoxicity: mechanisms of immune and non-immune small lymphocyte mediated target L cell destruction." <i>J Immunol</i> . 1968 Jul; 101(1):111-20.		
	C25	Gray, P.W. "Molecular characterization of human lymphotoxin." <i>Lymphokines</i> . 1987; 13:199-208.		
	C26	Gray, P.W., <i>et al.</i> "Cloning and expression of cDNA for human lymphotoxin, a lymphokine with tumour necrosis activity." <i>Nature</i> . 1984 Dec 20-1985 Jan 2; 312(5996):721-4.		
	C27	Green, L.M., <i>et al.</i> "Cytotoxic lymphokines produced by cloned human cytotoxic T lymphocytes. I. Cytotoxins produced by antigen-specific and natural killer-like CTL are dissimilar to classical lymphotoxins." <i>J Immunol</i> . 1985 Dec; 135(6):4034-43.		
	C28	Green, L.M., <i>et al.</i> "Rapid colorimetric assay for cell viability: application to the quantitation of cytotoxic and growth inhibitory lymphokines." <i>J Immunol Methods</i> . 1984 May 25; 70(2):257-68.		
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	C29	Hiserodt, J.C., <i>et al.</i> "Identification of membrane-associated lymphotoxin (LT) on mitogen-activated human lymphocytes using heterologous anti-LT antisera in vitro." <i>Cell Immunol.</i> 1977 Dec; 34(2):326-39.	
	C30	Itoh, N., <i>et al.</i> "The polypeptide encoded by the cDNA for human cell surface antigen Fas can mediate apoptosis." <i>Cell.</i> 1991 Jul 26; 66(2):233-43.	
	C31	Jones, E.Y., <i>et al.</i> "Structure of tumour necrosis factor." <i>Nature.</i> 1989 Mar 16; 338(6212):225-8.	
	C32	Kasid, A., <i>et al.</i> "Human gene transfer: characterization of human tumor-infiltrating lymphocytes as vehicles for retroviral-mediated gene transfer in man." <i>Proc Natl Acad Sci USA.</i> 1990 Jan; 87(1):473-7.	
	C33	Kinkhabwala, M., <i>et al.</i> "A novel addition to the T cell repertory. Cell surface expression of tumor necrosis factor/cachectin by activated normal human T cells." <i>J Exp Med.</i> 1990 Mar 1; 171(3):941-6.	
	C34	Kriegler, M., <i>et al.</i> "A novel form of TNF/cachectin is a cell surface cytotoxic transmembrane protein: ramifications for the complex physiology of TNF." <i>Cell.</i> 1988 Apr 8; 53(1):45-53.	
	C35	Liang, C.M., <i>et al.</i> "Production and characterization of monoclonal antibodies against recombinant human tumor necrosis factor/cachectin." <i>Biochem Biophys Res Commun.</i> 1986 Jun 13; 137(2):847-54.	
	C36	Liu, C.C., <i>et al.</i> "Identification, isolation, and characterization of a novel cytotoxin in murine cytolytic lymphocytes." <i>Cell.</i> 1987 Nov 6; 51(3):393-403.	
	C37	Liu, C.C., <i>et al.</i> "Identification and characterization of a membrane-bound cytotoxin of murine cytolytic lymphocytes that is related to tumor necrosis factor/cachectin." <i>Proc Natl Acad Sci USA.</i> 1989 May; 86(9):3286-90.	
	C38	Luetting, B., <i>et al.</i> "Evidence for the existence of two forms of membrane tumor necrosis factor: an integral protein and a molecule attached to its receptor." <i>J Immunol.</i> 1989 Dec 15; 143(12):4034-8.	
	C39	Mallett, S., <i>et al.</i> "A new superfamily of cell surface proteins related to the nerve growth factor receptor." <i>Immunol Today.</i> 1991 Jul; 12(7):220-3.	
	C40	Old, L.J. "Tumor necrosis factor (TNF)." <i>Science.</i> 1985 Nov 8; 230(4726):630-2.	
	C41	Paul, N.L., <i>et al.</i> "Lymphotoxin." <i>Annu Rev Immunol.</i> 1988; 6:407-38.	
	C42	Paul, N.L., <i>et al.</i> "Lymphotoxin activation by human T-cell leukemia virus type I-infected cell lines: role for NF-kappa B." <i>J Virol.</i> 1990 Nov; 64(11):5412-9.	
	C43	Pennica, D., <i>et al.</i> "Human tumour necrosis factor: precursor structure, expression and homology to lymphotoxin." <i>Nature.</i> 1984 Dec 20-1985 Jan 2; 312(5996):724-9.	
	C44	Peterson, A., <i>et al.</i> "Monoclonal antibody and ligand binding sites of the T cell erythrocyte receptor (CD2)." <i>Nature.</i> 1987 Oct 29-Nov 4; 329(6142):842-6.	
	C45	Pociot, F., <i>et al.</i> "A tumour necrosis factor beta gene polymorphism in relation to monokine secretion and insulin-dependent diabetes mellitus." <i>Scand J Immunol.</i> 1991 Jan; 33(1):37-49.	
	C46	Ranges, G.E., <i>et al.</i> "Tumor necrosis factor-alpha as a proliferative signal for an IL-2-dependent T cell line: strict species specificity of action." <i>J Immunol.</i> 1989 Feb 15; 142(4):1203-8.	
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	C47	Ranges, G.E., <i>et al.</i> "Tumor necrosis factor alpha/cachectin is a growth factor for thymocytes. Synergistic interactions with other cytokines." <i>J Exp Med.</i> 1988 Apr 1; 167(4):1472-8.	
	C48	Roodman, G.D., <i>et al.</i> "Tumor necrosis factor-alpha and hematopoietic progenitors: effects of tumor necrosis factor on the growth of erythroid progenitors CFU-E and BFU-E and the hematopoietic cell lines K562, HL60, and HEL cells." <i>Exp Hematol.</i> 1987 Oct; 15(9):928-35.	
	C49	Rosenberg, S.A., <i>et al.</i> "Use of tumor-infiltrating lymphocytes and interleukin-2 in the immunotherapy of patients with metastatic melanoma. A preliminary report." <i>N Engl J Med.</i> 1988 Dec 22; 319(25):1676-80.	
	C50	Ruddle, N.H. "Lymphotoxin redux." <i>Immun. Today.</i> 1985; 6:156-9.	
	C51	Ruddle, N.H., <i>et al.</i> "Cytotoxicity mediated by soluble antigen and lymphocytes in delayed hypersensitivity. I. Characterization of the phenomenon." <i>J Exp Med.</i> 1968 Dec 1; 128(6):1237-54.	
	C52	Ruddle, N.H., <i>et al.</i> "The role of lymphotoxin in inflammation." <i>Prog Allergy.</i> 1988; 40:162-82.	
	C53	Sastry, K.J., <i>et al.</i> "HIV-1 tat gene induces tumor necrosis factor-beta (lymphotoxin) in a human B-lymphoblastoid cell line." <i>J Biol Chem.</i> 1990 Nov 25; 265(33):20091-3.	
	C54	Schall, T.J., <i>et al.</i> "Molecular cloning and expression of a receptor for human tumor necrosis factor." <i>Cell.</i> 1990 Apr 20; 61(2):361-70.	
	C55	Scheurich, P., <i>et al.</i> "Immunoregulatory activity of recombinant human tumor necrosis factor (TNF)-alpha: induction of TNF receptors on human T cells and TNF-alpha-mediated enhancement of T cell responses." <i>J Immunol.</i> 1987 Mar 15; 138(6):1786-90.	
	C56	Shalaby, M.R., <i>et al.</i> "The involvement of human tumor necrosis factors-alpha and -beta in the mixed lymphocyte reaction." <i>J Immunol.</i> 1988 Jul 15; 141(2):499-503.	
	C57	Sigel, M.B., <i>et al.</i> "Production of antibodies by inoculation into lymph nodes." <i>Methods Enzymol.</i> 1983; 93:3-12.	
	C58	Smith, C.A., <i>et al.</i> "A receptor for tumor necrosis factor defines an unusual family of cellular and viral proteins." <i>Science.</i> 1990 May 25; 248(4958):1019-23.	
	C59	Spriggs, D.R., <i>et al.</i> "Tumor necrosis factor expression in human epithelial tumor cell lines." <i>J Clin Invest.</i> 1988 Feb; 81(2):455-60.	
	C60	Tavernier, J., <i>et al.</i> "Conserved residues of tumour necrosis factor and lymphotoxin constitute the framework of the trimeric structure." <i>FEBS Lett.</i> 1989 Nov 6; 257(2):315-8.	
	C61	Thomas, H., <i>et al.</i> "Biological approaches to cancer therapy." <i>J Int Med Res.</i> 1989 May-Jun; 17(3):191-204.	
	C62	Turner, M., <i>et al.</i> "Human T cells from autoimmune and normal individuals can produce tumor necrosis factor." <i>Eur J Immunol.</i> 1987 Dec; 17(12):1807-14.	
	C63	Tschachler, E., <i>et al.</i> "Human retrovirology: constitutive expression of lymphotoxin (tumor necrosis factor beta) in HTLV-I-infected cell lines." Raven Press, 1990; pp. 105-13.	
	C64	Watanabe-Fukunaga, R., <i>et al.</i> "Lymphoproliferation disorder in mice explained by defects in Fas antigen that mediates apoptosis." <i>Nature.</i> 1992 Mar 26; 356(6367):314-7.	
	C65	Ware, C.F., <i>et al.</i> "Mechanisms of lymphocyte-mediated cytotoxicity. II. biochemical and serologic identification of a precursor lymphotoxin form (pre-LT) produced by MLC-sensitized human T lymphocytes in vitro." <i>J Immunol.</i> 1981 May; 126(5):1927-33.	
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	C66	Ware, C.F., <i>et al.</i> "Human T cell hybridomas producing cytotoxic lymphokines: induction of lymphotoxin release and killer cell activity by anti-CD3 monoclonal antibody or lectins and phorbol ester." <i>Lymphokine Res.</i> 1986; 5(4):313-24.			
	C67	Ware, C.F., <i>et al.</i> "Regulation of the CTL lytic pathway by tumor necrosis factor." <i>Cellular Immunity and the Immunotherapy of Cancer</i> . UCLA Symposia on Molecular and Cell Biology, M.T. Lotze and O.J. Finn, Eds., 1990; 135:121-8 (Wiley-Liss Inc., New York).			
	C68	Ware, C.F., <i>et al.</i> "Expression of surface lymphotoxin and tumor necrosis factor on activated T, B, and natural killer cells." <i>J Immunol.</i> 1992 Dec 15; 149(12):3881-8.			
	C69	Wysocki, L.J., <i>et al.</i> "'Panning" for lymphocytes: a method for cell selection." <i>Proc Natl Acad Sci USA.</i> 1978 Jun; 75(6):2844-8.			
	C70	Yamanaka, H.I., <i>et al.</i> "Identity of human B-cell line cytotoxic lymphokine with tumor necrosis factor type beta." <i>Proc Natl Acad Sci USA.</i> 1989 Feb; 86(4):1343-7.			

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